Truth in Fiction: Appreciating the Complex Realities of the Pharmaceutical Industry Through Novels

PART I

Section I. Introduction

Who says that learning law can't be fun? The law schools, the professors, and even the students – that's who. But while the teaching and learning of law maintains its often dry, impersonal, and abstract qualities in academia, its true dynamism nevertheless triumphs in the real world of conflict, power, greed, pride, money, and human suffering. Sound like all the elements of a suspense novel? It certainly does.

Unlike textbooks, novels provide readers with colorful illustrations of the complexities and depths integral to the understanding of particular topics. Yet because of the traditional structure of courses and textbooks, subjects are often taught in overly simplified and compartmentalized ways so that sometimes the most interesting, humanizing, and engaging aspects of a topic remain unexamined. Law courses are no exception to this phenomenon and although topics such as criminal, administrative, corporate and tort law are in the real world highly complex, interesting, and often emotive, these multi-dimensional characteristics are overshadowed by the emphasis on the black letter law. Yet without a contextual understanding of the law, its relations to and effects on organizations, people, situations, time periods, and political climates, students remain bored and uninspired – not able to appreciate the law's true dynamism.

By presenting and addressing real-life problems through their storyline, characters, and relationships, novels may provide law students with the ability to "paradigm shift," to "examine the law from different perspectives" so that students' understandings of the law's roles in society may be both expanded and deepened.[1]

In this paper, I will illustrate how, through the use of fiction, both the teaching and learning of law may be made more interesting, meaningful, and fun. Section II begins with a discussion on the multiplicity of benefits and beneficiaries when fiction is incorporated into legal education. Section III illustrates how a topic like the pharmaceutical industry, its challenges, ethical issues, and relationships with governments and the public, may be best understood and appreciated when presented through the medium of novels.

Part II introduces the five novels selected for this paper and provides analysis of their portrayals of the pharmaceutical industry. This section briefly assesses each novel's plot, major characters, and the various issues and questions each book raises with regard to the challenges and roles drug companies play in society.

Part III provides a hypothetical lesson plan that uses the selected books to teach students about the pharmaceutical industry. The lesson plan incorporates a multi-faceted approach which uses the novels and excerpts from such novels as tools for learning, discussion, and contemplation.

Section II. Benefits of Incorporating Fiction to Legal Education

A. For Students

[1] Jean C. Love, *The Value of the Narrative in Legal Scholarship and Teaching*, 2 J. Gender Race & Just. 87, 88 (1998).

One of fiction's greatest gifts is providing the reader with the ability to "experience vicariously both the life and culture of the characters."[2] Too often, a law student's understanding of a case is limited to a court opinion, a substantially condensed analysis of a case which may have gone on for years. Although a judge or jury may have had the opportunity to see and hear from the various participants in a case, a student is denied such an opportunity and necessarily cannot fully appreciate the law's impact on society. Although it would be impossible for students to gain all the various perspectives involved in a case, novels, rather than court holdings, allow students a fuller scope of analysis. Through novels, students may benefit from the experiential world, one that is not limited by personal experience or prior knowledge.

Since most traditional students have limited life experiences and little, if any, interaction with real clients, the reading of novels exposes them to a "larger range of emotions and complexities in relationships than they would have access to otherwise."[3] Although a student may read a case where a woman gives birth to a deformed baby due to having taken morning sickness medication, the student remains uninformed about the many important factors that affect the woman's life, factors critically relevant in analyzing the relevant merits of her lawsuit: the extent to which such a tragedy has effected her family and professional life, the reasons for her deciding to pursue a lawsuit, her need for financial assistance, her relationship with her baby and family, her emotional and psychological difficulties, and her possible interactions with other parties similarly injured. Court opinions may briefly mention some of these factors, but can not address each factor with the attention and consideration it deserves. Yet, without an understanding of the *context* in which the

[2] Janet Cosbey, *Using Contemporary Fiction to Teach Family Issues*, 25 Teaching Sociology 227, 228 (1997).
[3] *Id.*

text of the law, regulatory agencies, and drug companies operate, a student's understanding of administrative regulations, policy concerns, and the role of the law, will be misguided or incomplete at best. Textbooks, devoid of narratives and in-depth personal stories that describe the unique situations, relationships, and stakeholders involved in a lawsuit, allow students to simply accept caselaw and statutes on their face, absent challenge, contemplation, or analytical inquiry.

On the other hand, fiction depends on the inclusion and analysis of the tangible and intangible, practical and theoretical, logical and emotional issues to successfully create and develop a compelling storyline. Through a comprehensive illustration of situations and problems necessary for the development of its plot, characters, and relationships, a novel frees students from their own interpretations limited by personal life experiences, and allows them to see situations through the eyes of different characters, often characters quite different from themselves. By reading about people and how the law has influenced the totality of their lives, students obtain a better understanding of people's lifestyles and "the reasons behind some of the choices they make."[4] It is only through the understanding of rationales and motivations that students may gain deeper insight into why people act certain ways and make the kinds of decisions they do.

> Through the novel, students were able to go places they might not otherwise have gone, meet people they might not otherwise have met, and experience lifestyles they might not have otherwise experienced.... Many of the students became more open to new ideas and to new perspectives... both personally and legally.... Many admitted they had formed opinions they though themselves incapable....[5]

[4] *Id.*

[5] Karin Mika, *Innovative Teaching Methods and Practical Uses of Literature in Legal Education*, 18 WHITTIER L. REV. 812, 815 (1997).

By understanding thought-processes, rationales, reactions, biases, and expectations, students will be better equipped to understand the potential dangers, limitations, and possibilities the law may play in society.

Moreover, learning through a novel with its grab-bag of drama, suspense, and romance is just plain fun! Instead of being averse to studying, students will at last embrace it – having always known that real life, embellished or not, deserved more attention and consideration than "just stating the facts."

B. For Teachers

Preparing lesson plans on the beach? Reading novels normally read during lazy summer vacations for class? These luxuries need not remain mere fantasies for the overworked, underpaid, and often uninspired law professor who may, like his students, accept that creativity, fun, and interactive discourse have no place in a law school classroom. With a little effort and a lot of imagination, the teacher, with the assistance of a few good stories, can give law the kind of life, complexity, and vitality that possesses in real life. With a method of teaching that fully involves the students and challenges them to think critically in both legal and non-legal terms, teachers will naturally be refreshed and inspired to facilitate in the opening of students' minds to new ideas and possibilities.[6]

In "Using Contemporary Fiction to Teach Family Issues," Janet Crosbey notes that

"[t]he advantage of having students use fictional works for their analyses is that the analysis is not done for the student but rather by the student... bringing the process of discovery to the students."[7] This analysis is especially true for law students whose study materials consist mainly of caselaw, opinions by individual judges

[6] *See id.*
[7] *Id.*

of how the law should be applied. Although students have opportunities to analyze a holding or opinion, their freedom to evaluate a case for themselves, weigh the relevant facts, and devise their own judgments, are necessarily tainted with the foreknowledge of an adjudicated outcome. By already knowing the court's holding and having read the court's opinion, students are no longer free to make independent conclusions on their own. Because most instructors encourage students' free thinking, so that students may formulate their own analysis rather than simply regurgitating an altered version of the teacher's or court's opinion, the efficacy of the novel is especially useful. Rather than directing students to think about situations in certain ways, novels, through its characters and situations, provide many perspectives from which the students can then develop their own unique evaluations.

Through the use of novels then, professors may truly encourage an environment of free-thinking. In this fictional environment, where although the stories and situations may be quite realistic, students need not worry that their analysis will be compared to those of judges and justices – intimidating benchmarks that may discourage students think creatively, freely, and independently.

C. For Classroom Discussions

> When discussing fiction, we can probe, criticize, and express ourselves freely without the constraints we feel when discussing real people. Good fiction lays bare the innermost thoughts and experiences of its characters, perhaps even their dreams and nightmares in a way that would be intrusive, uncomfortable, or impossible, even in autobiography.[8]

Again, learning through the use of novels connotes a notion of freedom that would otherwise unlikely be

[8] Dena S. Davis, *Tell Me a Story: Using Short Fiction in Teaching Law and Bioethics*, 47 J. of Legal Educ. 240, 241 (1997).

present in a classroom discussion, an element of class discourse that is

beneficial for both students and instructors. Novels open doors to new paths of discovery that are often unexplored in traditional classroom settings, paths not of facts and legalese, but journeys that find value in the importance of understanding people's innermost thoughts, hopes, biases, and personal experiences. Whether a law student becomes a litigator, a transactional lawyer, or a government official, understanding factors that motivate, inspire, discourage, and challenge people require more than just an understanding of substantive and procedural law. What one learns about people's perceptions of the law and how it is actually implemented and effectuated is equally important as understanding the substance of the law itself. Moreover, novels provide a point of reference from which all students, regardless of experience, background, or culture, may all identify.

> Throughout our class discussion, it is extremely helpful to have the short story as part of our shared material... where all the students refer to the story during our discussions and use it to make points about our topic.... Most students feel that the story has helped them push beyond the obvious.... Once they get beyond the strangeness of being asked to read fiction in law school, most students find it a helpful and enjoyable experience.[9]

Thus, fiction helps to facilitate class discussion by providing a common ground, "shared material" from which discourse may stem.[10] Because students bring with them their own unique set of beliefs, backgrounds, and biases, it may often be difficult for them to evaluate situations from any other perspectives but their own, thereby hindering their ability to appreciate alternative viewpoints and sensitivities.

> When the entire class reads a story, it provides a pool of shared experience, a fixed point for discussion. Just as we refer repeatedly to major cases over the course of a semester, these stories become part of our "bodied stuff on which to feed" and enrich class

[9] *Id.* at 245.
[10] *Id.*

discussions in unpredictable ways.[11]

Therefore, in providing a common ground from which students may experience situations through the eyes of the novels' characters, the stories give voices to those individuals students would otherwise unlikely hear: the voice of a man with terminal cancer, a homeless single mother, a defendant charged with murder, or an immigrant factory worker exposed to toxic chemicals. These individuals, often the ones around whom class discussion revolves, are also the ones with whom the average law student has little or no interaction. Therefore, if class discourse about social policy, administrative standards, and safety requirements is to have any genuine meaning, there must be a greater understanding of those very individuals most affected by such laws and policies. Here again, novels may provide the most fitting and accessible way from which students may gain this kind of knowledge and insight. Although it would be impossible for a student to obtain a comprehensive understanding of each individual he reads about in a case study, novels provide an intermediate medium through which students may gain greater insight to the kinds of struggles both legal and non-legal that people confront in various contexts. Whether it be the experiences of someone facing criminal charges, fighting a terminal illness, or struggling to raise a family on welfare, novels help students identify and be sensitive to specific factors affecting such individuals' lives, experiences unlikely to have influenced an average law students' life.

As a group in general, law students are a privileged class – living in safe neighborhoods, raised in loving families, and educated in elite institutions. For students to simply read the facts of a case or a short excerpt on an individual's life is far from truly appreciating the struggles and sensitivities of the individuals whose misfortunes and tragedies fill legal textbooks. The development of a genuine sense of compassion, empathy, and understanding of a person's problems and struggles comes only after observation and understanding of

[11] *Id.* at 241.

an individual's daily routines, relationships, challenges, thoughts, hopes, and dreams – those very elements that make for a compelling and engaging narrative.

D. For Outside Relationships and Social Understanding

In the recent true-story movie "Erin Brockovich," Julia Roberts plays a woman who helps win one of the largest class action tort cases in the country. Although the character Erin did not have a law degree nor legal experiences, her ability to communicate with the local townspeople, who made up the over four hundred individuals to the class, allowed her to gain their trust, support, and loyalty – a crucial factor which ultimately helped win the case. Although other lawyers representing the class tried to convince the townspeople to join in the lawsuit, they failed to do so due to their inability to appreciate the people's goals, concerns, and sensitivities. Moreover, the lawyers' formalistic and legalistic demeanor, so stereotypical of the profession, did little to ameliorate the situation. Although the movie's portrayal of these lawyers may have been exaggerated, the rift that often separates lawyers from their clients and the general public undoubtedly exists in the real world. Even with all of its dramatization and glamorization, this Hollywood movie nevertheless revealed social attitudes about the law and legal profession that exist and pervade in the real world.

Because "many people rely on popular culture for their understanding of law and the legal system," mass media and popular culture create powerful public impressions and expectations."[12] This phenomenon is

[12] *Id.*

especially true in the American society where "if compared to the cultures of other nations, the dominant culture of the United States is strikingly legalistic."[13]

> Day in and day out, legal institutions play significant roles in the resolution of sociopolitical problems, and – more subtly – legal terms, images, and scenarios infuse American conversations and imaginations.[14]

It is for this very phenomenon then, that understanding public attitudes and popular culture is especially important for law students. Unlike scientists, computer programmers, investment bankers, or academics, a lawyer's livelihood depends on her ability to adhere to people's expectations. Deviating from these expectations, even when they are unfounded, may cause a lawyer to lose clients, credibility, and even respect. Therefore, if a lawyer aspires to transcend stereotypes rather than being encumbered by them, she must first be aware of the stereotypes and their roots.

Fiction provides a powerful medium through which impressions are formed. When law students learn law through textbooks, cases, and statutes, they remain unskilled in the art of lawyering – the ability to work with law to benefit clients in their particular circumstances. Absent an understanding of public expectations and biases of the legal process and profession, a lawyer cannot be effective in his communications with and his understandings of clients, whose impressions of the law and legal system may be rooted in the images created by the pervasive American media. Fiction "can show the legal profession how they are perceived

[13] David Ray Papke, *The Advocates Malaise: Contemporary American Lawyer Novels*, 39 J. ON LEGAL EDUC. 413, 413 (1987).
[14] *Id.*

by the general public and can provide a 'common ground' of shared understanding which can be a starting point for discussion between lawyers and non-lawyers."[15] Therefore, just as fiction provides the "shared understanding" between participants in the classroom, it is also a bridge by which law students – future lawyers – may better understand the expectations and perceptions of their clients.

Section III. The Pharmaceutical Industry – A Perfect Model

Law is a central component of the democratic State. It defines the relation between the government and its people and sets the rules (and limits) of the restrained warfare of politics. Law becomes the battleground for moral debates.[16]

There is perhaps no other business where the cross-section of law, government intervention, morality, and mortality is more pressing than in the pharmaceutical industry. Human lives, suffering, hope, and tragedy hang on to one side of the scale while practical safety, profitability, efficiency, and reputational concerns remain on the other. Therefore, the fullness, depth, and complexity of issues facing the pharmaceutical industry make for the study of such a topic difficult, multi-layered, and often controversial. Although these elements, in a traditional course, may be addressed in a confusing and fragmented manner, they also provide all the appropriate elements for the development of engaging, dramatic, and realistic stories, ones that have the potential to capture students' hearts and imaginations.

One of the major characteristics of the pharmaceutical industry, that makes the novel, and not the textbook, a fit representative is its multiplicity of relationships in changing combinations that involve a wide range of

[15] Paul R. Joseph, *A Course Whose Time Has Come: Using Science Fiction Materials to Teach Law*, 22 Alternative L. J. 111, 111 (1997).
[16] *Id.*

personalities: drug company representatives, FDA officials, parties, lawyers, medical experts, government investigators, family doctors, injured patients, courts, and politicians. It is through an understanding of these relationships, their subtleties, sensitivities, and histories that lend insight to a student's appreciation for the rationale and thought-processes

that produce court decisions, agency rulings, and party actions.

Another aspect that makes novels an appropriate medium through which students may better learn about the pharmaceutical industry, is that the lives of the people most affected by such an industry cannot be fully appreciated from a textbook summary. With problems, struggles and "often conflicting wishes of the people who love and care for them," the sick and the suffering experience difficult, emotional, and personal challenges not quantifiable nor categorize-able in an orderly textbook fashion."[17] With hopes and fears to communicate, and anger and frustration to express, an illustration of these people, who depend on drug companies to take away their pain, free them from depression, and save their lives, can only be complete by the telling of their stories.

Section IV. The Next Step

With Part I having enumerated the many benefits novels may contribute to legal education and the additional insights they provide, Part II presents concrete examples of just how expansive, both in depth and scope, novels may be in covering a particular topic. This paper's chosen topic is the pharmaceutical industry, and the following novel commentaries will show that this area of study, far from being boring, is highly complex, interesting, and engaging.

[17] Davis, *supra* note 3 at 240.

PART II – NOVEL SUMMARIES & COMMENTARIES

Acceptable Risk by Robin Cook

Robin Cook has always been on the cutting edge of the latest medical controversies. In Acceptable Risk, he confronts one of the most provocative issues of our time: personality-altering drugs and the complex moral questions they raise. Neuroscientist Edward Armstrong has managed to isolate a psychotropic drug with a strange and dark history – one that may account for the public hysteria during the Salem witch trials. In a brilliant designer drug transformation, it is developed into an antidepressant with truly startling therapeutic capabilities. But who can be sure the drug is safe for consumers? Who defines the boundaries of "normal" human behavior? And if the drug's side effects are proven to be dangerous – even terrifying – how far will the medical community go to alter their standards of... acceptable risk?[18]

Acceptable Risk raises a plethora of issues confronting pharmaceutical companies, the medical profession, and the general public with respect to the safety, limitations, and dangers of drugs. By highlighting these issues, Cook takes his readers into a deeper layer of inquiry, evaluating such things as: the essence of humanity, the danger of a society too dependent on quick fixes, and the value of human suffering and pain.

While developing these often abstract and theoretical questions that induce readers to stop and think about their own humanity, priorities, dependencies, and beliefs, Cook educates his readers on a wide spectrum of topics – some directly and others surprising related, if somewhat tenuously, to the drug business. Readers learn about the general processes of financing a drug company, limitations established by the National Institute of Health ("NIH") and FDA for the

[18] Robin Cook, Acceptable Risk book jacket (1994).

medical profession and pharmaceutical industry, differences between how medical professionals operate in academia versus in industry, and how experiments are conducted for new drugs. Moreover, Cook creates a story within his own story by adding a historical dimension to the role of drugs on society, through an analysis of the Salem witch trials.

The multitude of issues Cook raises is effectively and realistically portrayed through the creation of believable and empathizable characters each of whom approach and respond to such issues with his or her own set of experiences and values. Some of the main characters are important to note:

- ***Edward*** the neuroscientist who initially, content with his life in academia, was won over with the lucrative possibilities of developing and marketing a new multi-billion dollar drug – fame, fortune, and power. Along with a change in priorities was a change in judgment so that medical caution and prudence gave way to business necessity and efficiency.

- ***Kim*** the nurse who sought to keep boyfriend Edward from losing all sense of objective perspective and rationality in his quest for the miracle drug. Kim herself, shy and insecure, struggles from being won over by Edward's convincing appeal that personality-altering drugs can be nothing but beneficial for individuals and society. In addition to her increasingly difficult confrontations with Edward, Kim has taken time from work to research the hanging of her ancestor Elizabeth during the Salem witch trials. With Edward's scientific expertise and her own research, Kim uncovers the significant role that drugs played even hundreds of years past in shaping social relationships and communities.

- ***Stanton*** the entrepreneur who is always looking for new business ventures. With his extensive connections and business savvy, Stanton convinces Edward to enter into a partnership with him and personally acquires all the financing for Edward's new lab and research team.

Strong Medicine by Arthur Hailey

Hidden addictions, treacherous politics, and deadly danger behind the locked doors of the multibillion-dollar drug industry. Miracles drugs save lives and ease suffering, but for profit-motivated companies, the miracle is the money they generate... at any cost. Billions of dollars in profits will make men and women do many things – lie, cheat, even kill. Now one beautiful woman will be caught in the cross fire between ethics and profits. As Celia Jordan's fast-track career sweeps her into the highest circles of an international drug company, she beings to discover the sins and secrets hidden in the research lab... and in the marketplace. Now the company's powerful new drug promises a breakthrough in treating a deadly disease. But Celia Jordan knows it may deliver a nightmare.[19]

[19] Arthur Hailey, Strong Medicine book jacket (1984).

By his meticulous research and penchant for detail, Arthur Hailey's 445 pages of *Strong Medicine* is jammed packed with insight on the drug industry: its internal operations, its relationships with private and governmental organizations, its accomplishments and failures, its history and future.

Readers gain this firsthand look into the depths and complexities of the pharmaceutical industry through Celia Jordan's career with Felding-Roth Pharmaceuticals from beginning until end. This twenty-eight-year journey begins in 1957 with Celia working as one of the first women in the Felding-Roth sales department and ends with her rise to the presidency of the company in 1985. In between those years, Celia takes the readers through a roller-coaster of experiences: the highs and lows of the pharmaceutical business, the changing political climates
and their effects on the industry, the internal workings and tensions of Felding-Roth, and her own struggles as a woman trying to succeed in a highly conservative and male-dominated industry.

Yet it is only through the input, reactions, and advice of others, that Celia's decisions and experiences gain greater depth and dimension. For better or worse, the other characters in Strong Medicine help to shape the many ethical issues raised in the book, all the while educating readers on the historical, political, and organizational changes facing the pharmaceutical industry over a span of almost thirty years. Some of the main characters are important to note:

- ***Celia Jordan*** the savvy career woman who diligently worked her way from being a "detail-sales" person to president of Felding-Roth Pharmaceuticals. During her scaling of the corporate ladder, Celia gains experience and insight into the various departments and

hierarchical echelons of the company and discover their unique tensions and challenges. At every step of her career, Celia confronts difficult decisions often where her personal ethics and business acumen pull in opposite directions. It is during these difficult times that Celia often looks to husband, Dr. Andrew Jordan, for advice and solace. Having personally witnessed the power and influence of pharmaceutical industries in the medical profession, Dr. Jordan provides Celia with the much needed medical expertise and insight to humanize and personalize the effects that drug industries have on doctors and patients. Through almost three decades of mistakes, triumphs, and tragedies, Celia Jordan's life with Felding-Roth takes readers to every corner and hiding place of the company.

- ***Dr. Andrew Jordan*** the medical doctor who strives support for his wife's work in the pharmaceutical industry, even though he often opposes the industry's practices and motives.

Although wife Celia does not always adhere to Andrew's advice, he never fails to voice his opinions – Celia's voice of conscience. Often serving as the bridge between those who produce drugs and those who consume them, Dr. Jordan possesses a unique perspective on both the benefits and harms to individuals and society by the drug industry. Not only is Andrew assertively vocal about his beliefs, his opinions about the role of drugs in society are also expressed in the way he advises both his clients and family members. He is especially concerned about the role of drugs during pregnancy, asserting that, "a drug should not be taken for anything that is just uncomfortable or self-limiting."[20] Dr. Jordan is a fitting foil for his wife Celia and through their communications, disagreements, and full scale arguments, readers gain a first-hand point-counterpoint debate on many important issues relating to pharmaceutical industries and the role that drugs play in society.

- ***Dr. Martin Peat-Smith*** the university scientist who is working to find a cure to a disease afflicting thousands of individuals, including his mother, every year – mental aging and Alzheimer's. Having been recruited by Felding-Roth to start up the Felding-Roth Institute in London, England, Dr. Martin Peat-Smith enters a new territory of research – research not simply for the advancement of science sake but for the advancement of business and profits. The transition Martin makes from academia science to corporate science is a difficult one in which many lessons are learned, mistakes made, and challenges faced. In addition to confronting such obstacles, Martin's laboratory is ransacked by animal rights activists, his competency questioned by a new staff, and his research controlled a corporate board of

directors.[21]

- ***Dr. Vincent Lord*** the chief scientist at Felding-Roth Pharmaceuticals for over two decades.

Although no longer the young, brilliant, and hopeful individual he was when he first started with the company, Dr. Lord nevertheless remains stubborn and prideful in the accuracy and

superiority of his medical analysis, thereby often resisting the kind of increased degree of caution and social consciousness promoted by Celia Jordan. An embittered man still trying to discover the miracle drug that will gain him the respect and fame he never attained,

Dr. Lord resorts to manipulation and blackmail to gain FDA approval for one of the company's drug applications. Dr. Lord's dream is to create a drug that quenches free radicals – a drug that would be added to other drugs to make those drugs safe. Dr. Lord often provides the scientific narratives that give significance to what would otherwise be meaningless and difficult to pronounce terms throughout the novel.

The Delta Factor by Thomas Locke

Two dedicated scientists – one a government regulator and the other a researcher – tinker with strands of genetic material in a quest to conquer viral disease. A miracle drug of immeasurable value – both commercial and humanitarian – lies at their fingertips. Yet a staggering discovery shatters their scientific assumptions, and they are pulled into a vortex of deception and corporate greed. These sinister powers will let nothing impede the drug's release – not even human life! Suspense and intrigue on the cutting edge of biotechnology.[22]

[21] *See id.* at 225.

[22] Thomas Locke, The Delta Factor book jacket (1994).

Having potentially found a new drug that would excite the immune system and strengthen it against viral attacks, Dr. Deborah Givens suddenly becomes the center of attention at Pharmacon, a second-tier pharmaceutical company that for many years struggled to resuscitate its business. Although Deborah's discovery possessed the potential to bring fame and fortune to the company, the new drug lacked one major element – it could yet not be manufactured synthetically.

Initial findings in a Central European root extract called echiniacin indicated that the drug retards the growth of virus-related illnesses and at times stops such illnesses from progressing altogether. Although the drug cannot cure, it can prevent viral infections and the exacerbation of illnesses caused by viruses. The ingredients used to develop the new drug were extracted and combined from several potentially active ingredients within the echin root, the development of which was not yet possible in a laboratory setting.

Although the compounds cannot yet be produced synthetically, Pharmacon is allowed to begins its FDA patent application. Moreover, having discovered how to increase the plant's growth rate while forcing the plants to change compounds naturally, Deborah decreases the length of time that the compounds would eventually be produced synthetically.

Yet Pharmacon's growing of the echin root in highly controlled environments result in the root's flowers emitting pollen with hallucinogenic effects that causes major chaos in the various farmlands on which echin roots are being grown.

Although Deborah faces many obstacles in her search to both naturally grow and synthetically create the echin root's compounds in just the exact amounts and combinations, the Pharmacon board, rather than helping to address her concerns, simply apply pressure to hasten her research, often choosing speed over caution. Outnumbered and out-bullied by her superiors at Pharmacon, Deborah turns to fellow scientist

and long-time friend Cliff Devon for guidance and help. As the FDA Consumer Safety Officer in charge of reviewing the new echin drug application, both he and Deborah find themselves in professionally and personally difficult positions as they simultaneously try to support each without violating their professional duties and loyalties.

This book provides especially detailed but clearly expressed explanations regarding the steps in which a new patent and drug applications are made and processed. Moreover, it also addresses the many challenges faced by FDA new drug review teams in their constant struggle to find a balance between ensuring public safety and providing relief for the suffering. This balancing act is made even more difficult when the pharmaceutical companies themselves, instead of looking to the public they are serving, have their eyes set on financial success. Some characters are important to note:

- ***Dr. Deborah Givens*** the Pharmacon research scientist who after revealing the Pharmacon board that she suffered from multiple sclerosis, an illness that could debilitate her at any time, was stripped of her chief researcher position. Although the board demoted Deborah and planned to fire her after a few token years, her discovery of the echin root's beneficial possibilities suddenly made Deborah an indispensable company asset. Having to face the potential worsening of her own disease, Deborah's discovery of a compound that could potentially strengthen the system against viral attacks as well as slow their damaging effects, has importance personal value. Hopeful for the first time since being diagnosed with MS, Deborah begins to take the new experimental drug herself. Because

MS is disease in which neither the cause is known nor what course the disease will pursuit, taking the drug provides Deborah no certain answers, only a hope that she never before allowed herself to have... hope. Therefore, the challenges Deborah faces are manifold: personal interest in creating an effective compound, pressure from the Pharmacon board to quickly create a drug approvable by the FDA and marketable to the public, and loyalty to her friend Cliff, a officer in the FDA who urges Deborah to not compromise scientific responsibility in light of personal or professional interests.

- ***Cliff Devon*** the FDA Consumer Safety Officer, whose team is in charge of the Pharmacon case. Having joined the FDA with the goal of "making the system better," Cliff begins to realize that the FDA environment can be marred by betrayal, jealously, and deception often for fraudulent profiteering.[23] Through his work in the FDA and the relationships he has there, Cliff provides readers a look into the inner workings of the FDA: the kinds of relationships it develops, the challenges and criticism it faces, and the overwhelming responsibility its review teams shoulder. Like a foil to Deborah, Cliff's relationship with her allows readers to gain insight into the various struggles pharmaceutical companies and the FDA have with each other, their various considerations and priorities, as well as how each entity approaches issues of health and safety, government pressure, and public criticism.

- ***Horace Tweedie*** the FDA officer who sought to make a fortune from his position in the FDA before his imminent retirement – one to which everyone in his files department anxiously awaited. Having watched everyone but himself rising in the FDA hierarchy, Horace deeply resented his government employer and eventually found a way to spite a

[23] *Id.* at 40.

place that did not recognize him for his talents and contributions. Working in the files department gave Horace access to all sorts of FDA data, initial trials, formulas, and doses which they then turned over to an agent of a Brazilian pharmaceutical company interested in Dr. Given's research. Throughout the novel, Horace attempts to obtain more information for the man he only recognizes in the dark inside a car with tinted window, a man with black hair, dark eyes, and a foreign accent. So while that Deborah works tirelessly to naturally and synthetically produce the perfect compound, Horace Tweed engages in his own profiteering escapade that adds to the suspense and complexity of the book.

The Third Patient **by George Mannis**

Dr. Paul Holden treats a critically ill patient one night while on call in a Philadelphia hospital. While determining the best course of treatment, he learns that the woman is a participant in a clinical study for a new drug. After he has passed the case on to the attending physician and specialists, the woman's children appeal to him for help. Could the experimental drug therapy be responsible for their mother's dire condition? Dr. Holden is moved by compassion and curiosity to look into the matter on behalf of the family. However, professional courtesy turns to hostility when Dr. Holden's inquiries start to make the medical establishment and the pharmaceutical company's representatives uncomfortable. Resistance and veiled threats only sharpen Dr. Holden's determination to find the truth. Medical research is a high stakes proposition with fortunes riding on FDA approval. To what lengths will drug companies go to prevent interference in getting their potentially lucrative products on the market? Dr. Holden may be risking his own life to find out. The Third Patient is an intelligent, fast-paced medical thriller that is chilling... and believable.[24]

By becoming the pharmaceutical company Gother's medical consultant, Dr. Paul Holden positions himself

[24]George Mannis, The Third Patient book jacket (1999).

at the heart of the company's operations and discovers first-hand to what lengths these companies will go to prevent interferences. No longer in a world where saving and protecting lives is the highest priority, Dr. Holden's new position in Gother often contradicts the ethical and professional responsibilities he swore to uphold as a medical doctor. Yet, because Paul's only way to uncover the truths to Goth's new drug Neurovan is to maintain his consultancy position, he has no choice but to go against his ethical judgments. Without enough inside information, Paul may only be able to slow down the Neurovan application process rather than completely eliminating any chance for FDA approval. But while Paul slowly and cautiously gather information on the drug and the truths about its experimental tests, Neurovan's approval in Europe and the United States become ever more imminent.

In his race against time, Paul quickly learns about the drug company and the masterminds who control it. He learns about how the company pursues its goals and to what lengths it will go to achieve them, what other important parties and individuals are critical to the drug company, and the relationships Gother establishes with its shareholders, the FDA, and the media. Throughout Paul's crash course on the ins and outs of the drug company and the pharmaceutical industry in general, readers have the opportunity to ride along through a mountain of facts, dramatizations, exaggerations, and subjective narratives from all sides of the drug debate.

These various perspectives are presented through a parade of characters ranging from medical professionals from England to the children of the deceased woman whose death was caused by Neurovan. It is their voices and experiences that give life and complexity to the multitude of issues caused and faced by the

pharmaceutical industry and FDA. Some characters are worth nothing here:

- ***Dr. Paul Holden*** is the doctor who, after treating a woman involved in a clinical study of a

new drug, becomes suspicious of the drug's efficacy and safety. His curiosity leads him to find out more about the drug Neurovan and eventually induces him to take on a consultancy position at Gother, the company that produces Neurvovan. While working for Gother, Paul attempts to find information that would substantiate his suspicion that Neurovan is not only

ineffective, but also unsafe. During this quest for facts and secrets, Paul not only learns about Gother and the drug industry, he faces the constant temptation of substituting ethical duties for fame and fortune – a tradeoff that many people seemed to have no problem making. But Dr. Paul Holden is steadfast and ultimately discovers and reveals the truths of

Gother and Neurovan.

- ***Dara Lyons*** the young Gother clinical associate who initially informs Dr. Holden about

the dangers and ineffectiveness of Neurovan. Struggling between whether to help Dr. Holden stop Gother from distributing an unsafe drug to the public or continuing her own professional upward climb in the company, Dara is a complex and conflicted character who vacillates between assisting the good and the corrupt. Through her character, readers also gain insight into the challenges facing women in the corporate world and the kinds of sacrifices and compromises women often think they must make to succeed.

- ***Dr. Gerald Lennox*** the Gother scientist who initially protested against Neurovan's

FDA application but eventually succumbed to corporate pressures. When Dr. Holden becomes a part of the Gother team, Dr. Lennox first attempts to evade Dr. Holden's inquiries regarding Neurovan's safety and efficacy. Yet with Dr. Holden's persistence and constant appeal to his conscience, Dr. Lennox finally regains his sense of commitment to his

E. The Choice by Barry Reed

Frank Galvin, a smart Irishman from the tough side of town, is the star litigator at a blue-chip Boston law firm. Faced with a crisis of conscience when a corporation his firm is representing is accused of causing birth defects in Boston's Portuguese population with its new drug, Frank suddenly finds himself on the wrong side of a ferocious legal war – hired to destroy the people he trusts, loyal to those he doesn't. The New York Times Book Review calls The Choice, the "first techno-thriller for lawyers... a seething potboiler.[25]

The Choice, written by a real-life name partner in a Boston law firm specializing in medical malpractice cases, focuses on the legal issues related to the pharmaceutical industry and its role in promoting public health and safety, a role which unfortunately can too often also endanger the public. It is this latter problem that pervades throughout the novel as Reed educates his readers of the many issues that arise when drug companies hurt when trying to help.

Frank Galvin is about to land a partnership in a top Boston firm when fledgling attorney Tina Alvarez asks for his help in a suite against Gammett Industries, whose miracle drug for heart disease, Lyosin, has produced birth defects in the children of her Portuguese clients. Because Gammett is already a firm client, Frank is obliged to turn down the case and then forced to defend the suit against Tina and the allies he found for her, including his old partner Moe Katz.

While heading the case, Frank is unaware that members of his legal team have advised Universal, Gammett's multinational parent corporation, to destroy and alter incriminating documents: backdating changes in Gammett's incorporation papers, changing the wording of various documents, and suppressing evidence that note the drug's active ingredient's detrimental side effects. Beginning to realize his fellow peers' improprieties

[25] Barry Reed, The Choice book jacket (1991).

and therefore thus Gammett's improprieties, Frank becomes even more conflicted with his dual obligations as a zealous advocate for his client and an honest officer of the court.

The complex web that begins to form within Frank also materializes externally as the book illustrates the many complex relationships that develop in a class action tort suit between and among doctors, insurance companies, witnesses, Gammett management, FDA officers, and members of the opposing parties. Some of these main players are important to note:

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deep-pocketed corporate giants.

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PART III – LESSON PLAN

Section I. Introduction

This particular lesson plan was created with the purpose of utilizing the selected books to provide greater scope and depth to students' understanding of the pharmaceutical industry. Due to the unconventional nature of this course-plan, this paper suggests that a combination of innovative and traditional teaching techniques will present the most efficacious way to assist students in their learning of this topic.

Structured to adhere to a winter term schedule, the course, with its extended class periods, attempts to address issues through different approaches that emphasize the importance of both student participation and instructor guidance. The daily assignments help prepare students for thoughtful class discourse and encourage them to think creatively and independently. Since each of the five selected books is over 300 pages, the assigned readings of one book a week, with additional articles and writing assignments, are only reasonable in a winter term when students have no other class-work. Each week focuses on one book and each day's lesson addresses a particular issue raised in the book.

Because the majority of class material is fictional, the need for a knowledgeable and informed professor, having had substantial experience with the pharmaceutical business, is especially important.

Although this particular lesson plan is structured with five books in five weeks, its prescribed schedule should not be interpreted as a constraint. Rather it should be viewed as a flexible guide, one that is adjustable to

suit particular curriculums and time constraints.

Section II. Class Format & Assignments

A.

Getting Started – Course Readings

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B.

-

-

C. Point-Counterpoint

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-

Section III. Daily Class Procedure

A.

Part 1 – Passage of the Day

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B.

Part 2 – Point-Counterpoint

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-

C.

Part 3 – Reality Check

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D.

Guest Speakers

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Section IV. Schedule of Topics & Daily Passages

A.

- **Monday – Starting a Pharmaceutical Company: Costs and Considerations**

" How much money can you raise?" Edward asked.
"How long do you estimate it would take before you were ready to market this new drug?" Stanton asked.
"I don't think I can answer that question," Edward said. "Obviously I can't even be one hundred percent sure it will ever be marketable."
"I know that," Stanton said. "I'm just looking for a best-guess estimate. I know that the average duration from discovery of a potential drug to its FDA approval and marketing is about twelve years, and the average cost is somewhere around two hundred million dollars. Obviously the shorter the development time and the less money needed means more equity we can keep for ourselves."

"How much money do you think you would need?" Stanton asked.
"I'd have to set up a state-of-the-art lab," Edward said.
"What's the matter with the lab you already have?" Stanton asked.
"The lab belongs to Harvard," Edward said. "I have to get the Ultra project away from Harvard because of a participation agreement I signed when I accepted by position.... The agreement concerns discoveries made on company time using company equipment.
"How about the development period?" Stanton asked. "How much shorter do you think you could make that?"
"A lot," Edward said. "One of the thing about Ultra that has impressed me is how unbelievably nontoxic it appears to be. I believe this fact alone will make FDA approval a breeze since characterizing specific toxicities is what takes so much damn time... Animal studies will be accelerated if there's no toxicity to worry about, and the clinical portion can be collapsed by combining phase II and phase III with the FDA's expedited schedule."
"The expedited plan is for drugs targeted for life-threatening diseases," Kim said.
"If Ultra is as efficacious for depression as I think it will prove to be," Edward said, "I'm confident we can make a case for it in relation to some serious illness."

" *I'll start raising the money and organizing the legal work to set up the corporation as well as to start the patent applications."*[26]

[Months later]

" *All right," Stanton said. "I'm beginning to think you used to work for the Pentagon, since everything you order is the most expensive available... The burden to keep this operation afloat falls on my shoulders. Unfortunately it ain't going to be an easy task with the rate you are going through you capital."*[27]

Article Reading:

Christine Dodd, *The Merck-Medco Merger: An Isolated Incident or a Catalyst for the Transformation of the Industry*? 63 U. Cin. L. Rev. 1767 (1995).

[26] Cook, *supra* note 13 at 185.

- **Tuesday – Personality-Altering Drugs**

I'm not in favor of using drugs for minor personality flaws like shyness. I think drugs should be reserved for serious problems, not mere everyday difficulties... As a nurse I see too many people taking too many drugs. Drug companies have got us to think there is a pill for every problem."[28]

Kim had always been suspicious of quick and easy solutions. Over the years she'd developed the opinion that the best way to deal with her problems was the old-fashioned way with introspection, a little pain, and effort.[29]

Kim explained to Edward that she'd thought about grief and expanded the notion to include anxiety and melancholy, saying that moderate amounts of these emotionally and painful feelings play a positive role as motivators of human growth, change, and creativity. She concluded saying, "What I am worried about is that taking a drug like Ultra that modulates these mental states may have a hidden cost and could cause a serious negative side effect that would not be anticipated."

"I appreciate your concern," Edward said. It's an interesting thought you have, but I don't share it. You see, it's based on a false premise, namely that the mind is somehow mystically apart from the material body. That old hypothesis has been debunked by recent experience that shows that the mind

" and the body are one even in regards to mood and emotion. Emotion has been proved to be biologically determined by the fact that it is affected by drugs like Prozac, which later levels of neurotransmitters. It has revolutionized ideas about brain and function.

"That kind of thinking is dehumanizing," Kim complained.

"Let me put it another way," Edward said. "What about pain? Do you think drugs should be taken for pain?"

"Pain is different," Kim said, but she could see the philosophical trap Edward to laying for her."

"I don't think so," Edward said. "Pain, too, is biological. Since physical pain and psychic pain are both biological, they should both be treated the same, namely with well-designed drugs that target only those parts of the brain responsible."

Kim felt frustrated. She wanted to ask Edward where the world would be if Mozart and Beethoven had been on drugs for anxiety or depression.[30]

Article Reading:

Peter Moleman et al., *Psychopharmacological Treatment of Personality Disorders*, *in* TREATMENT OF PERSONALITY DISORDERS 207 (Jan Derksen et al. eds., 1999).

- **Wednesday – Cosmetic Psychopharmacology: Possibilities & Limitations**

> *There was no place for drug-induced self understanding, or drug induced assertiveness, or a drug induced happy mood. It was all fake. The concept of cosmetic psychopharmacology disgusted her.*[31]

Article Reading:

Len Sperry & Harry Prosen, *Contemporary Ethical Dilemmas in Psychotherapy: Cosmetic Psychopharmacology and Managed Care*, 52 Am. J. of Psychotherapy 54 (1998).

- **Thursday – Drug Researchers: Self-Experimentation**

“

When do you think we can start marketing in Europe and Japan?” Stanton

asked.
“ *We’ll have some idea once we start clinical trials,” Edward said. “But that*

won’t happen until we get the IND from the FDA.”

“ *We’ve got to speed up the process somehow,” Stanton said. “This is crazy!*

We’ve got a billion-plus drug and we could be bankrupt.”

“ *Wait a second,” Edward said. “I just thought of a way to save some time. I’ll*

start taking the drug myself... With the results of the toxicity studies we’ve already done, I’m confident to take Ultra without the slightest qualm.”

“ *How will it save time?” Stanton asked.*
“ *Hell, we’ll have all the answers before we even begin clinical trials,” Edward*

said. “Think how easy it will make designing the clinical protocols.
One by one the other researchers agreed that it was a fabulous idea and offered to participate.

“ *We can all take different dosages,” Gloria said. “And six people will even give*

us a modicum of statistical significance when trying to evaluate the results."

Isn't taking an unapproved investigational drug against the law?" Kim asked.
" *"What kind of law?" Edward asked with a laugh. "An institutional review board law? Well, as far as Omni goes, we are the institutional review board."*
"I thought the government had guidelines or laws about such things," Kim

persisted.

" *The NIH has guidelines," Stanton explained. But they are for institutions*

receiving NIH grants. We're certainly not getting any government money."

Kinnard started to climb into his car when Kim stopped him.
" *I have a question for you," she said. "Is it against the law for researchers to*

take an experimental drug that has yet to reach clinical testing?"

" *It's against FDA rules for volunteers to be given the drug," Kinnard said.*
" *But if the researchers take it, I don't think the FDA has any jurisdiction. I can't*

imagine when they would sanction it, and it might cause trouble when they attempt to get an Investigational New Drug Application."
" *If they are, it would raise a significant ethical issue," Kinnard said.*
There would be the question of coercion with the more junior members... taking an uninvestigated drug is not a smart idea," Kinnard said. "There is too much risk of unexpected side effects."[32]
" Article Reading:
Seth Roberts & Allen Neuringer, *Self-Experimentation*, *in* HANDBOOK OF RESEARCH METHODS IN HUMAN OPERANT BEHAVIOR 619 (Kennon Lattal et al. eds., 1998).

• Friday – Limits to Animal Testing

"

It's our own fault," Gloria said. "We should have known better than to start

taking the drug until all the toxicity studies were completed."
I don't see that would have made any difference," Edward said. "To this day, no animal
" *studies have shown this human side effect. In fact, by our own taking the drug when we did, we probably saved a large number of human volunteers from experiencing what we've suffered."*[33]

Article Reading:
Fabrice N. Vincent, *Hotly Contested Controversy Over Experts: Can Animal Studies*

Apply to Humans? 2 Fen-Phen Litig. Strategist 1 (2000).

B. Strong Medicine by Arthur Hailey

- **Monday – The Organization of a Pharmaceutical Industry**

Felding-Roth, like other big pharmaceutical firms, erected a wall between the prescription drug portion of its business, which was considered prestigious, and it's O-T-C activities which frequently were not. On each side of the wall all activities were separate. Each side had its own administration, research staff, and sales force; there was no liaison between the two. A prescription drug costs millions to research and takes five, six years before it's ready for selling. With an O-T-C item, you need six month or less to formulate the stuff, and the cost is peanuts. After that the big money goes for packaging, advertising, sales. People who've got something wrong with 'em – mostly something minor which time would take care of it they had the sense to leave it alone – those people want to treat themselves. They like playing doctor, and that's where we come in. There are a few good things – like aspirin. As to others, the main thing is they make people feel good, even if it's only in their minds.[34]

A perpetual tug-of-war existed between sales and manufacturing on the one hand and research on the other. As the sales people expressed it, "Research always wants to be a hundred and ten percent sure of every goddamn detail before they'll say, "Okay, let's go!" Manufacturing similarly, was eager to gear up for production and not be caught out by sudden demands when a new drug was required in quantity. But, on the other side of the equation, researchers accused the merchandising arm of "wanting to rush madly onto the market with a product that's only twenty percent proven, just to beat competitors and have an early lead in sales."[35]

[34] Hailey, *supra* note 19, at 107.
[35] *Id.* at 105.

Article Reading:

Michael A. Weber, *Impact on the Pharmaceutical Industry of Changes in the American Health Care System: A Physician's Perspective*, 24 Seton Hall l. Rev. 1290 (1994).

• Tuesday – Significance of History in Shaping the Pharmaceutical Industry

> *Nothing in the drug industry would ever be quite the same again after the facts of Thalidomide became well-known. In West Germany, in April 1961, physicians were startled by an outbreak of phocomelia – a rare phenomenon in which babies are born tragically deformed, without arms or legs, instead having tiny, useless, seal-like flippers... Many of the babies had other defects as well as missing limbs. Ears were absent or deformed; hearts, bowels and other organs were incomplete or didn't function as they should... Then in November 1961, two doctors working independently and unknown to each other – a pediatrician in Germany and an obstetrician in Australia – linked phocomelia to the drug Thalidomide. Soon afterward, it was established that the drug was indeed the cause of the defective births.... Australian authorities, acting swiftly, ordered Thalidomide off the market during the same month the connection become known. West Germany and Britain withdrew the drug a month later... But in the United States it was two months more until, in February 1962, the Thalidomide-Kevadon application was withdrawn from the FDA. Canada, inexplicably left the drug on sale until March – four months later than the Australian withdrawal and time for many more individuals, including pregnant women, to take it.*[36]

Article Reading:
Sally-Anne Danner, The Vaccine Ailment: A Cure to Encourage Litigation-Shy Pharmaceutical Companies to Manufacture an Aids Vaccine, 14 Hamline J. Pub. L. & Pol'y 67 (1993)

• Wednesday – Politics and the Pharmaceutical Industry

"

You may not find those activist people – Maud Stavely, Sidney Wolfe, Ralph

Nader and the others – easy to live with, and at times you may detest them," Andrew said. "But you need them, your industry needs them, just the way General Motors and the other auto companies needed Nader before he alighted on the scene. Nader helped make automobiles – for all of us – better and safer because of his needling and I, for one, am grateful."[37]

> *A United States senator has enormous power and influence, in some ways even more than a President because the exercise of power is less visible. There isn't a government department a senator can't reach into and have something done, providing it isn't outrageous or illegal. Important people inside and outside government will fall over themselves to do a senator a favor, even if that favor is harmful to someone else. It's a system of trades and, within that system, a senator's power – which can be used benevolently or to destroy – is the biggest trading chip of all. Which is why it's a foolish person indeed who chooses to make an enemy of a U.S. senator.*[38]

Article Reading:
Paul E. Kalb & I. Scott Bass, *Government Investigations in the Pharmaceutical Industry: Off-Label Promotion, Fraud and Abuse, and False Claims*, 53 Food & Drug L.J. 63 (1998).

- **Thursday – Relationships Between the Medical Profession and the Drug Industry**

> *Doctors often became "successful addicts," undetected for long periods, because of the ease with which they could obtain drugs... the fact that physicians could get free supplies of any drug, virtually in unlimited quantity, merely by asking a detail man from the company concerned.*[39]
>
> *Companies surround doctors with drugs! They deluge them! With sleazy, oh-so-clever, limitless advertising, page after page in medical magazines which doctors have to read, and with an avalanche of mail, and with free trips and hospitality and booze – all of it designed to make doctors think drugs, always drugs, and still more drugs! The companies, every one of them, swamp doctors with free samples, telling them they can have any drug they want, in whatever quantity, and just by asking! No restrictions, never any questions!"*[40]

"

[37] *Id.* at 270.

Article Reading:

Susan Heilbronner Fisher, *The Economic Wisdom of Regulating Pharmaceutical "Freebies*," 1991 DUKE L.J. 206 (1991).

- **Friday – International Effects and Concerns**

> *Do you know what theses are?"*
> *"Of course I don't!" Dropping into chair, Celia peeled off her shoes and left them where they fell. "What's more I don't care!"*
> *"You should care! Those are Thalidomide and I bought them today in a local drogueria – without a prescription."*
> *"The fact that I could buy them five years after they should have been withdrawn, and buy other dangerous drugs marketed here without proper warnings because there are no government agencies to insist on adequate labeling, is typical of the don't-give-a-damn attitude of American drug firms, including your own precious Felding-Roth!"*[41]
>
> *I know that pregnant women who take these tablets will have babies with flippers instead of arms. Do you know what the pharmacist told me today? He said, yes he had heard about Thalidomide, but he didn't know these tablets were the same things because they're called Ondasil. And in case you don't know, Celia, or don't want to know, Thalidomide has been sold by drug companies under fifty-three different names. Why always so many different names for drugs? Certainly not to help patients or their doctors. The only reason anyone can think of is to sow confusion and aid the drug firms when there's trouble."*[42]
>
> Article Reading:
> Bryan L. Walser, *Shared Technical Decisionmaking and the Disaggregation of Sovereignty: International Regulatory Policy, Expert Communities, and the Multinational Pharmaceutical Industry*, 72 TUL. L. REV. 1597 (1998).

C. The Delta Factor by Thomas Locke

- **Monday – Organization of the FDA**

The Food and Drug Administration occupied one large portion of the federal rabbit warren in Rockville, Maryland, situated about an hour's drive north of Washington, D.C. The building housed various departments of Health and Human Services of which the FDA was one. Almost six thousand people worked in the concrete beehive. His first week on the job, Cliff had gotten lost between the main entrance and his office, then again between his office and the cafeteria – even finding the restroom had

been a major feat. The FDA building was about as user-friendly as a tax form.[43]

At any one time, each [FDA] team member worked on up to a dozen drug applications. Each new drug application contained several hundred thousand pages of reports and trial data through which they had to sift. Marybeth Schuler, their statistician, checked the figures and the math. Martin Corelli, their chemist studied the complex molecular formulas. Ben Travers flipped back to the summary of drug indications. And Dana Browning, still a physician at heart, concentrated on the individual case-study reports.[44]

Article Reading:
Elizabeth C. Price, *Teaching the Elephant to Dance: Privatizing the FDA Review Process*, 51 Food & Drug L.J. 651 (1996).

- **Tuesday – FDA Approval for New Drugs**

Obtaining FDA approval for a new drug was a multiphase process. Including pretrial testing and development that had to take place before initial application, the procedure lasted well over five years.

[43] Locke, *supra* note 22, at 34.
[44] *Id.* at 86.

After the initial analysis and synthesis, the new drug had to be tested in animals. A safe dosage for humans had to be worked out. Initial claims for benefits had to be developed and possible side effects – known as contraindications – established. And then a representative like Harvey Cofield would appear at the FDA office, present reams of preliminary documents, and make the Investigational New Drug application. Only after the IND was approved could clinical trials on humans – and the actual FDA approval process – begin.

Phase one of the clinical trials usually involved between twenty and one hundred human subjects. This normally occurred over a three-to six-month period and concentrated upon safety. During this time, the medical doctor on the FDA team would conduct a safety review.

Phase Two involved the first tests upon human subjects actually suffering from the ailment which the drug claimed to treat. This was where the detailed case studies began. Phase-two testing usually involved between one and three hundred patients and took something over one year. Phase three followed, with more than a thousand patients treated, and if the drug passed this hurdle it would be approved.

On average, research and development and application for a new drug cost more than two hundred million dollars. For every drug that won FDA approval, nine were turned down. For the drugs that were approved, however, the payoff could be mind boggling.

Newly approved drugs had on average seven years left to run on their original patent. For those seven years, no other company was allowed to produce that drug, and prices could be set as high as the market would bear. For ground-breaking new medicine, the market could bear an enormous amount.

A new ulcer drug recorded first-year revenues of seven hundred million dollars. A new migraine drug cost seventy dollars for two doses and was expected to earn almost two billion dollars in the first eighteen months of its release.

Political and media pressure to accelerate FDA approval was commonly exerted, but usually not before phase-three testing had been underway for at least a year. Approval prior to this time was simply too dangerous. Until a drug had been tested on a large number of patients over a substantial period, there was too much risk of something going wrong, of some unforeseen side effect appearing. No drug company could afford to take such a chance.[45]

Article Reading:
Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. Rev. 93 (1999).

- **Wednesday – Analogues**

An analogue drug was one in which a minute change had been made to an already licensed medicine. In some few cases, the change of one molecule in a complex drug erased a whole host of bad side effects. But in the majority of applications, the analogue was a smokescreen.
Some pharmaceutical companies used analogues to renew aging patents; they would make minor alterations and then claim that a new drug had been discovered. Other companies used them to skirt around patent-protected medicines, claiming to have come out with something newer, better, stronger. Analogues were headaches from the onset, primarily because the drug companies did everything in their power to cloak their own hidden agendas behind a veil of data and gobbledygook.[46]

Article Reading:

Robert A. Bohrer & John T. Price, *A Tale of Two Proteins: The FDA's Uncertain*

Interpretation of the Orphan Drug Act, 12 Harv. J.L. & Tech 365 (1999).

- **Thursday – International Patenting**

De Cunhor and his colleagues in the Brazilian pharmaceuticals industry were no respecters of international patents. They did not ignore U.S. patent laws, however; the United States was too strong a political and economic force for them to publicly flaunt their disregard. Instead, they maneuvered around the laws in a uniquely Brazilian manner.

Every major Brazilian drug manufacturer had at least one government patent official on their payroll. For suitable sums, that official would be most willing not only to back-date an application, but also to "lose" the international paperwork that notified other countries. A new Brazilian drug could thus be copied from an existing one, the production process begun, and the market penetrated before an official protest from the United States could be lodged. Legal challenges to such abuses of patent infringement were expensive and often futile. International tribunals were slow to take action, and Brazilian courts moved on such complaints at the pace of arthritic snails. In many instances, by the time the case was actually tried, the patent's validity had already expired.
Most of the American pharmaceutical giants responded to this threat by establishing their own Brazilian factories, protecting themselves and their patents by operating within the same corrupt system. The Brazilian drug companies thus focused their search-and-copy missions to second-tier companies that did not produce in their market.[47]

Article Reading:

Robert Weissman, *A Long, Strange Trips: The Pharmaceutical Industry Drive to*

Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 U. Pa. J. Int'l Econ. L. 1069 (1996).

- **Friday – Use of Natural Roots and Herbs for Drugs**

So she comes up with this idea to look into some natural medicines used behind the Iron Curtain... or what used to be the Iron Curtain. Medicine is so backward there, they're still using roots and herbs from the Middle Ages. We thought, what the heck, it wouldn't cost much, and who knows, she might actually turn up with something... A number of key medicines had been discovered in just such studies of natural healing elements. Digitalis, used for heart failure, came from the foxglove plant. Taxol, a new drug used in the treatment of ovarian cancer, had been recently isolated from the bark and needles of the Pacific yew tree.
"Biosynthetic drugs are manufactured in the laboratory, naturally occurring drugs are derived from materials found in the physical world. Pharmaceutical companies prefer to work with biosynthetic drugs. Aspirin, for example, was discovered first in the natural world, then eventually a means was found to manufacture it in the lab."
"Why is that so important?"
"Because its easier and eventually cheaper. With naturally occurring drugs, we have to find methods of purification to remove any harmful substances in the final product. Then we have to prove that we will obtain the same pharmacological response every time... We have to prove that the dose from this batch of plants will have exactly the same effect as the one from the next batch. We call it validation of the process, where every batch has the same purity and potency, time after time."[48]
Article Reading:Amy Guerin Thompson, *An Untapped Resource in Addressing Emerging Infectious Disease: Traditional Healers*, 6 Ind. J. Global Legal Stud. 257 (1998).

D. The Third Patient by George Mannis

- **Monday – The Wallstreet Business of Drugs**

Different drug companies have different ways of communicating with Wall Street analysts. Some form special ties with one or two brokerage houses and then feed them periodic updates. Other companies announce every achievement as it happens, minor as

it may be. This is done mostly to get a bump in the stock price. Gother has a biannual meeting with analysts who cover the pharmaceutical industry.[49]

Article Reading:

Mark v. Pauly, *The Impact of Health Reform on the Pharmaceutical Industry*, 24 SETON HALL L. REV. 1271 (1994).

- **Tuesday – Clinical Trials: Procedures and Processes**

" *I want to investigate the practices of these companies when they run clinical trials. I'm especially interested in what the patient knows when he signs that form. I want to know how informing that consent form really is."*[50]

Article Reading:

Robert A. Prentice, *Clinical Trial Results, Physicians, and Insider Trading*, 20 J. Legal Med. 195 (1999).

- **Wednesday – Drug Companies & FDA Committees**

" *Don't you see? To get Neurovan approved, they need somebody to explain the liver problem. What can they do? They go through consultants. If they find a somewhat friendly consultant, they try to buy him off. Money travel, computers. Anything goes."*

" *But what if the consultant is negative?"*
"You mean, if he's slightly negative and about to become a member of a key FDA committee? They neutralize him. They try to buy him off. If he stays negative, he'll have to excuse himself from discussing Neurovan at FDA meetings. But there is always the chance that he'll turn around and become positive, because of the perks they shower on him."
" *So, part of the reason for hiring me was to neutralize me as a possible adversary at FDA hearings?*

[49]Mannis, *supra* note 24, at 279.

" *Exactly," she says.*
"But even if I become positive about their drug, I still have to excuse myself

during advisory committee discussions of Neurovan?"

" *Of course, but then you still can help them in all the other countries. Remember,*

the US is less than one third of the world market for this drug."[51]

Article Reading:Sidney A. Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288 (1986).

- **Thursday – Foreign Equivalents of the FDA**

The Commission on the Safety of Medicines, or CSM for short, is the body responsible for approving new chemical entities as drugs for sale in the United Kingdom. It is the British equivalent of the FDA, and has the reputation of a fair-minded yet tough and demanding scientific body. Unlike the FDA it only gets involved once all the clinical studies are complete, and has no say or interest in advising the companies what to do in advance.[52]

Article Reading:
David V. Eakin, The International Conference on Harmonization of Pharmaceutical Regulations: Progress or Stagnation? 6 TULSA J. COMP. & INT'L L. 221 (1999).

- **Friday – FDA Medical Monitors**

A medical monitor like Aftaz, although not considered to be a top executive position in the FDA hierarchy, still wields a lot of power. If he likes a particular drug and recommends its approval, it usually sails through the advisory committee rapidly and gets approved. If he has any doubts, if he has any questions, if he isn't convinced by the results, a monitor can become very stubborn. Sometimes his questions can cost drug companies tens of millions of dollars, because he has the authority to demand new long, expensive clinical trials. It could also delay approval and marketing by many years.[53]

Article Reading:
Larry R. Versteegh, Science and Regulatory Rituals Associated with the Drug Development Process, 52 FOOD & DRUG L.J. 155 (1997).

[51] *Id.* at 123.

E. The Choice by Barry Reed

- **Monday – The Drug Tradeoffs**

" *These are the victims that Lyosin is going to help – would-be cripples, thousands upon thousands. There are side effects to any drug – even aspirin can precipitate a heart attack in certain people. There's no such thing as a perfectly harmless drug – and the law doesn't exact perfection. Any war has its share of innocent casualties."*
"Now your reporter writes an article bad-mouthing Lyosin... He not only does a disservice to the people dependent upon the drug but also works a cruel hoax on these families whose children are supposedly affected. He builds up false hope that they'll win millions of dollars."[54]

Article Reading:

Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 Seton Hall L. Rev. 1481 (1994).

- **Tuesday – A Triad of Responsibility: Doctors, Drug Companies & FDA**

" *It is not important for any medical practitioner to have exact knowledge of the countless plants, herbs, or compounds that make up the vast array of pharmacologic drugs. In fact, such omniscience would be impossible. This knowledge is for the chemist and the pharmaceutical firms. Busy practitioners prescribing medications have to rely on the knowledge and integrity of established drug companies."*
" *The drug Lyosin is well known to me. I have prescribed it in the New Bedford and Fall River communities since it first came on the market some then years ago. It was highly touted as a cure for heart disease. Now the drug companies know more about the drug, its efficacy, safety, side effects, and complications than anyone. They have inside information."*
" *Now, an increased number of birth defects began cropping up in the* communities of Fall River and New Bedford about six or seven years ago... The

[54] Reed, *supra* note 25, at 24.

percentage was too high to be prescribed to chance. I wrote to Gammett's medical director in 1984, advising him of my findings. I never received a reply. I also wrote to the FDA and received a terse response from that source, thanking me for my interest and advising that the drug was considered safe, and even efficacious."

" *My suspicion and findings were never acknowledged by the manufacturer. And the top policing organization on prescription drugs refused to look into the matter."*[55]

Article Reading:

Barry R. Furrow, *Enterprise Liability for Bad Outcomes From Drug Therapy: The Doctor, The Hospital, The Pharmacy, and The Drug Firm*, 44 Drake L. Rev. 377 (1996).

- **Wednesday – Insurance Companies & Tort Reform**

> *There's a national media blitz for tort reform, especially favoring manufacturers. They claim product liability insurance is forcing them out of business. The whole charade is being orchestrated by the insurance industry. Got to hand it to them, Madison Ave. sure knows how to be effective. Thirty-seven states have enacted ceilings on damage awards, and now the Kalb bill carves out the final sanctuary of privilege. Favors manufacturers of shoddy products, corporate polluters, drunk drivers. No one's going to be held accountable anymore.*[56]

Article Reading:

Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern American Tort Law,* 26 Ga. L. Rev. 601 (1992).

- **Thursday – The Business Entity: Principal-Agent Issues**

[55] *Id.* at 136.

> *Personnel hired by or terminated by Gammett shall be subject to Universal's approval." This covered the clerk in the mailroom right up to Dr. Torgenson. No question about it. Universal had complete control over Gammett. Gammett was merely a cardboard corporation. Given such a contractual*
>
> " *agreement, any fair-minded judge would rule that Universal was doing business in Massachusetts. Service of process on Gammett would bind Universal. Even Frank Galvin and all the legal talent at Hovington, Sturdevant, Holmes & Hall couldn't pull that one out.*[57]
>
> Article Reading: Annotation, *Products Liability: Necessity and Sufficiency of Identification of Defendant as Manufacturer or Seller of Product Alleged to Have Caused Injury*, 51 A.L.R. 1344 (1973).

- **Friday – The History of Medicinal Herbs and the People Who Discovered Them**

" *Now, in Aubrey's day, heart disease wasn't discussed as it is today. People*

lived and died. There were various epidemics and no one got terribly alarmed when

> *someone clutched his chest and keeled over, least of all in Burma. Death was merely a transition, a reincarnation. But Aubrey, during one of his tiger hunts into the wide and remote Naga Hills – noted that the Changareet, an offshoot of the Kachins, seemed to live forever. As in Shangri-la, people survived to a ripe old age. By Aubrey's calculation, many lived well into their nineties. Keep in mind that this was at the turn of the century when the average Asian survived only to his mid-thirties.... After years of living in the jungle, researching and running down medicinal herbs and exotic plants, Aubrey finally discovered the secret of the Changareet. It was this little nut called the correiga, indigenous to the jungles of Northern Burma, a kind of betel nut, one of the staples of the Changareet. They chew it, brew it, cook it, and smoke it."*[58]

Article Reading:
Lester I. Yano, *Protection of the Ethnobiological Knowledge of Indigenous Peoples*,
41 UCLA L. Rev. 443 (1993).

CONCLUSION

In a world with few easy answers, courses that try to simplify fields of study by compartmentalizing, categorizing, and condensing issues may do students more harm than good. In trying to make a subject more clear, consistent, and concise, a teacher may be encouraging students to develop misguided impressions and biases, deterring them from fully appreciating and being sensitive to the inherent complexity of most life subjects and situations. Moreover, attempts at simplification may indirectly extract from a topic's dynamism and realism – the very elements that make for studying a subject interesting and engaging.

In providing summaries and analysis of five fictional stories, this paper tried to illustrate that novels, rather than serving merely as mediums for relaxation and personal enjoyment, can also be used as educational tools, even in the legal field. Although not all law school courses can use the narrative approach, many courses such as criminal law, civil procedure, human rights, government, and food and drug law may greatly benefit from the incorporation of the novel in their lesson plans.

A novel's power to inspire, engage, and excite while serving educational goals should not be underestimated. Through the reading of these five books, I have not only retained more factual detail regarding the pharmaceutical industry than I ever thought possible, I also gained a greater understanding of the many tensions, challenges, and pressures confronted by people working with, for, and against this industry. By having the opportunity to see through the eyes of a medical scientist, a malpractice lawyer, a sick child, a worried mother, a FDA examiner, and a frustrated doctor, I experienced and witnessed the conflicts, tragedies, excitements, frustrations, and hopes so much a part of the pharmaceutical industry. It was not until after having read these books that I finally understood what Professor Peter Hutt meant when he said he loved his job with the FDA because it was so interesting and exciting. With the assistance of these novels, not only

have I gained greater insight into the pharmaceutical industry, but a greater appreciation for the significant role it plays in our society and our lives.